

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
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PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference 2345.2046002		Date of Mailing (day/month/year) 11 JUL 2006
International application No. PCT/US03/34801		REPLY DUE within 1 months/days from the above date of mailing
International filing date (day/month/year) 31 October 2003 (31.10.2003)	Priority date (day/month/year) 01 November 2002 (01.11.2002)	
International Patent Classification (IPC) or both national classification and IPC IPC: C12Q 1/68( 2006.01) USPC: 435/6.91.2		
Applicant DECODE GENETICS EHF.		

- This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
- This opinion contains indications relating to the following items:
  - ☒ Basis of the opinion
  - ☐ Priority
  - ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☐ Lack of unity of invention
  - ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Certain documents cited
  - ☐ Certain defects in the international application
  - ☒ Certain observations on the international application
- The applicant is hereby **invited to reply** to this opinion.
 

**When?** See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
- The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 01 March 2005 (01.03.2005)

Name and mailing address of the IPEA/US  
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I. Basis of the opinion

1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☒ the description:  
 pages 1-91, as originally filed  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
 pages 92-101, as originally filed  
 pages NONE, as amended (together with any statement) under Article 19  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the drawings:  
 pages 1-299, as originally filed  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages NONE, as originally filed  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

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## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 4-44 and 46-51

because:

☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 4-44 and 46-51.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. STATEMENT**

Novelty (N)	Claims <u>1-3 and 45</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-3 and 45</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-3 and 45</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-3 and 45, with respect to considered species SNP at 16802968) meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method for detecting a predisposition to type II diabetes that utilizes the detection of a polymorphism in a SLIT-3 nucleic acid.

Claims 1-3 and 45 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1-3 and 45, as they relate to species SNP at 168029068 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because of the claims not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because: The claims are drawn to detecting a predisposition to developing type II diabetes by detecting a polymorphism in a SLIT-3 nucleic acid. The claims are broadly drawn to include the use of any possible polymorphism within a SLIT-3 nucleic acid. The description teaches a sequence provided in figure 10 which is a SLIT-3 nucleic acid, and gives a list of polymorphisms within this gene in Table 11. The description does not provide an analysis of any or all of these individual SNP, in particular not for the SNP at position 168029068. It is highly unpredictable which SNP within the SLIT-3 nucleic acid will be reliably associated with the phenotype type II diabetes, and thus, for the broad claims the description does not provide adequate enablement. Likewise, it is highly unpredictable whether or not the single polymorphism 168029068 will be associated with the phenotype type II diabetes and so even for the claim 3 which was considered for this polymorphism the practice of the claimed invention is not enabled at least because of the lack of teaching in the specification and the highly unpredictable nature of the invention.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

**TIME LIMIT:**

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.